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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/942,588	08/31/2001	Nobuko Yamamoto	35.C15717	9425

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EXAMINER	
SIEW, JEFFREY	
ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 01/30/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/942,588	YAMAMOTO ET AL.	
	Examiner	Art Unit	
	Jeffrey Siew	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 August 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) *1,5,14,15,21 and 22* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 August 2001* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *8* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Specification

1. The specification contain nucleotide sequences that not identified by proper SEQ ID Nos. Correction is required.

Claim Objections

2. In claim 1 the word "totally" is misspelled. Also in claim 1 the passive voice in "are originated" is objected to .

3. In claim 1 it is suggested that the word "are" be deleted and "further comprise" be incorporated for clarity.

4. Claims 5 is objected to because the language " corresponding to the selected region of the step (d) to obtain a second pattern" is grammatically unclear. The step already is in step d and selected region **is** the region selected previously not one that is corresponding.

5. Claim 14, 15,21 & 22 are objected to for minor language informalities. It is suggested e.g. 8-30 nucleotides be incorporated.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claim 7 is grammatically confusing. The passive voice makes the claim unclear as to what limitation is imparted on the substrate and/or method

B) Claim 8 is indefinite. It is unclear at which detection in step d signal is to be detected thus calling variation positive.

C) Claim 9 recites "when reacting with a normal base sequence of a nucleic acid.". It is unclear the connection with the rest of the claim. Correction is required.

D) Claims 1-24 are indefinite. It is unclear what would constitute a "normal sequence". The terms target sequence and variant sequences are suggested

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 16,17, 19 & 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Lipshutz et al (US5,733,729 March 31 , 1998).

Lipshutz et al teach a computer system and detector for detecting fluorescence intensities of chip for base calling variant sequences on a biochip (see whole doc. esp. col. 7 lines 1-35). They teach the system has a scanner including a detector such as using a confocal microscope of CCD that detects location of labeled probes (see col. 5 lines 30-40).

Applicant is reminded that the claims is drawn to product claims and read in so far as the physical limitations.

> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

8. Claims 1,2,5-16 & 19-23 are rejected under 35 U.S.C. 102(e) as being anticipated by Cronin et al (US6,309,823 Oct. 30, 2001).

Cronin et al teach a array and method to detect mutations using the array in which different regions correspond to different probe sets that are complementary to reference sequence and mismatch sequences (see whole doc. esp. abstract). They teach that the probes may be of various lengths e.g. 15 base pairs (see col. 11 lines 17-25). They teach that variation of interrogation position of probes may be detected by comparing presence of mutation of single mismatch probe with a double mismatch probes (see col.12 lines 29-45). The probes are each are arranged in column orders corresponding to the A,C,GT lanes (see col. 13 lines 54-65). They also teach that the hybridization of target and reference may be performed sequentially and the analyzed by comparing the signals of the target sequence with the reference to determine the variation (see col. 17 lines 10-45 & col. 14 lines 20-39). The array are immobilized by cell or different regions and include a blank cell (see col. 2 lines 6-18) .They teach a system for detecting the chip (see figure 21).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2,3 17 & 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cronin et al (US6,309,823 Oct. 30, 2001) in view of Drmanac (US6,309,824 oct. 20 2001).

The teachings of Cronin et al are described previously.

Cronin et al do not explicitly teach fluorescent or chemiluminescent labels.

Drmanac teach the use of fluorescent or chemiluminsecent labeling in probe arrays (see col. 6 lines 15-18).

One of ordinary skill in the art would have been motivated to apply Drmanac's labelng techniques to Cronin et al's hybridization assay in order to provide for efficient and safe detection of bound hybrids. As chemiluminiscent and fluorescent labels were well known and commonly used at the time the invention was made, it would have been prima facie obvious to apply Drmanac's teachings in order to successfully and efficiently detect hybridized targets in Cronin et al's assay.

10. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lipshutz et al (US5,733,729 March 31 , 1998) in view of Drmanac (US6,309,824 oct. 20 2001).

The teachings of Lipshutz et al are described previously.

Lipshutz et al do not explicitly teach fluorescent or chemiluminescent labels.

Drmanac teach the use of fluorescent or chemiluminsecent labeling in probe arrays (see col. 6 lines 15-18).

One of ordinary skill in the art would have been motivated to apply Drmanac's labelng techniques to Lipshutz et al's hybridization assay in order to provide for efficient and safe detection of bound hybrids. As chemiluminiscent and fluorescent labels were well known and commonly used at the time the invention was made, it would have been prima facie obvious to apply Drmanac's teachings in order to successfully and efficiently detect hybridized targets in Lipshutz et al's assay.

SUMMARY

11. No claims allowed.

CONCLUSION

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Siew whose telephone number is (703) 305-3886 and whose e-mail address is Jeffrey.Siew@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can best be reached on weekdays from 6:30 a.m. to 3 p.m. If attempts to reach

the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist for Technology Center 1600 whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-3290 and Before Final FAX (703) 872-9306 or After Final FAX (703) 30872-9307.

Jeffrey Siew

January 27, 2002